

REMARKS/ARGUMENTS

Claims 1-24 were pending in this application. Claims 1, 17, and 24 have been amended. No claims have been added or canceled. Hence, claims 1-24 remain pending. No new matter enters by way of the present amendment, and no further search or consideration is required. As such, entry of the present amendment and reconsideration of the subject application as amended is respectfully requested.

Examiner Interview

Examiner Patel is thanked for the courtesy of the telephonic interview conducted on June 15, 2006. Present on the line at the interview were Examiner Patel, as well as inventor Dr. Keith G. Lurie, and Applicants' representatives, Darin J. Gibby and Milan M. Vinnola.

The content of the previous final Office Action, as well as the cited reference, U.S. Patent No. 5,377,671 to Biondi, *et al.*, were discussed during the interview. Applicants' representative explained the teachings of Biondi, and it was agreed that Biondi did not disclose or suggest extracting respiratory gases from the person's airway to create an intrathoracic vacuum so as to maintain a negative pressure. The inventor further discussed the enhancement of blood flow back to the heart upon creation of a negative intrathoracic pressure. Support for the previous claim amendments in the specification as originally filed was pointed out. However, it was discussed that such limitations were not needed to distinguish the cited art.

In sum, the Examiner agreed that Biondi did not teach or suggest the claimed invention, and agreed to reconsider the present claims upon filing of this amendment and response.

Claims Rejected Under 35 U.S.C. 112, First Paragraph

Claim 17 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This rejection is respectfully traversed.

As discussed during the interview, support for the amendment may be found at least, e.g., at paragraph [0082] of the application as originally filed (or paragraph [0080] of the published application). However, because the limitation is not needed to distinguish over the

cited art, this limitation has been deleted without prejudice or disclaimer. Further, this amendment, nor the corresponding amendments to independent claims 1 and 24, do not narrow the scope of the claims in any regard.

Double Patenting Rejections

Claims 1, 3, and 4 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claim 1 of U.S. Patent No. 6,938,618 to Lurie, *et al.* (hereinafter "Lurie"). Claims 1, 3 and 7-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claim 1 of copending Application No. 10/660,462. Claims 17 and 20 are also provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claim 1 of copending Application No. 10/660,462 in view of U.S. Patent No. 5,685,298 to Idris (hereinafter "Idris").

Applications respectfully traverse. However, in order to facilitate prosecution, Applicants submit herewith terminal disclaimers over U.S. Patent No. 6,938,618, as well as copending Application No. 10/660,462. Nonetheless, Applicants note that the filing of a terminal disclaimer to obviate a rejection based on nonstatutory double patenting is not an admission of the propriety of the rejection. *See Quad Environmental Technologies Corp. v. Union Sanitary District*, 20 U.S.P.Q.2d 1392 (Fed. Cir. 1991). The court indicated that the "filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection."

Rejections under 35 U.S.C. § 103(a)

Claims 1-24 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over the cited portions of U.S. Patent Application No. 5,377,671 to Biondi, *et al.* (hereinafter "Biondi"). This rejection is respectfully traversed for at least the reasons which follow.

The Examiner acknowledges that Biondi does not disclose the ranges of different system parameters, such as breath delivery time and date, vacuum pressure and intrathoracic pressure levels. However, in support of the rejection, the Examiner alleges that it would have

been obvious to one of skill in the art to optimize the most effective variables to achieve optimal results, such as reducing intracranial pressures. Again, Applicants respectfully traverse.

Although Biondi may mention in passing extraction of a portion of the volume of respiration gas from the lungs of the patient, “under either subambient or substantially ambient respiratory gas pressure,” as discussed during the Examiner interview, such disclosure merely relates to the manner in which respiratory gases are actually extracted from a subject, i.e., using a vacuum source. There is no teaching or suggestion regarding the creation of subambient conditions within the patient, the desirability of maintaining negative pressures in the thorax, or any suggestion of the benefit of such negative pressures in the treatment of subjects suffering from any particular ailments. In fact, as acknowledged by the Examiner during the interview, Biondi discloses and exemplifies only atmospheric and positive intrathoracic pressures, e.g., see Fig. 3C. Further, Biondi teaches that ventilatory function may result in an interference with cardiac function as a result of the positive pressure applied to the lungs and generated by the expanding lungs. This positive pressure, if applied during the diastolic or filling phase of the cardiac cycle, increases the pressure around the heart and compresses the veins returning blood to the heart, thereby preventing the heart from filling and ejecting adequately.

Moreover, Biondi does not teach or suggest to one of skill in the art a correlation between negative intrathoracic pressures and a reduction in intracranial pressures. As such, it is submitted that one of skill would not be motivated, based on the teachings of Biondi, to optimize the method of Biondi to achieve results related to reducing intracranial pressures. Instead, as discussed above, Biondi teaches the importance of timing the respiratory gas introduction and extraction portions of the ventilatory cycle so as to be synchronous with portions of the cardiac cycle. However, Biondi is completely silent with regard to any specific correlation between negative intrathoracic pressures and the treatment of subjects or the increase of blood flow, much less the importance of maintaining a negative intrathoracic pressure.

As such, Biondi teaches the importance of timing the respiratory gas introduction and extraction portions of the ventilatory cycle so as to be synchronous with portions of the cardiac cycle. However, Biondi is completely silent with regard to any specific correlation

between negative intrathoracic pressures and the treatment of subjects or the increase of blood flow, much less the importance of maintaining a negative intrathoracic pressure. Instead, Biondi focuses on the effects of positive pressure during the diastolic phase of the cardiac cycle. Absent such teachings, Biondi does not disclose each and every element of the claims. For at least these reasons, withdrawal of this rejection is respectfully requested.

As such, whatever else Biondi may disclose, absent a suggestion of creating an intrathoracic vacuum, or of the desirability of maintaining a negative intrathoracic pressure, one of skill in the art would not identify the specifically claimed system parameters as result effective variables to optimize in the manner claimed. *See, e.g.* MPEP 2144.05(II)B. Based on the teachings of Biondi, one of skill in the art would look to optimize the timing of inspiration and expiration cycles around the cardiac cycle rather than around maintaining a negative intrathoracic pressure. As such, one of skill in the art would not be motivated to modify the teachings of Biondi so as to arrive at the present invention. As such, withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 303-571-4000.

Respectfully submitted,

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